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09/866,067	05/23/2001	Thomas J. Meade	A-58762-20/RFT/RMS/RMK	7813

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/866,067

**Applicant(s)**

MEADE ET AL.

**Examiner**

Frank W Lu

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's response to the office action filed on June 29, 2005 and August 1, 2005 have been entered. The claims pending in this application are claims 21-32. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's response filed on August 1, 2005.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. New Matter

Claims 21-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the specification describes 2' or 3' modified nucleotide triphosphate (see page 21, last paragraph) and deoxyribonucleoside triphosphates (see specification, page 40, first paragraph), the specification does not adequately describe that a nucleotide triphosphate comprising a covalently attached transition metal complex which is an electron transfer moiety as recited in claims 21-32. MPEP 2163.06 states that "If new matter is added to the claims, the

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examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” In view of the embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of products encompass in the claims at the time of the application was filled. Therefore, the written description requirement has not been satisfied.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V.*

*Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a “written description of the invention” which is separate and distinct from the enablement requirement. The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the “applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

### ***Response to Arguments***

In page 6, second paragraph bridging to page 7, first paragraph of applicant’s remarks, applicant argues that: (1) “[F]irst, claims 24-26 and 27-32 are not new matter. Adequate support for the claims is provided in the specification as filed to reasonably convey to one skilled in the relevant art that Applicants had possession of the claimed invention at the time the application was filed. For example, the paragraph starting on page 21, line 17 describes the addition of an electron transfer moiety to nucleosides. The paragraph starting on page 21, line 29 describes the making of a 2’ or 3’ modified nucleotide triphosphate. Furthermore, the paragraph starting on page 33, line 3 describes the use of ruthenium or iron (as well as other metals) as part of the transition metal complex”; and (2) “[S]econdly, the same rejection was raised by Examiner S.

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Zitomer in an Office Action dated May 20, 2003. A timely response traversing the rejection was filed and overcome the rejection”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, although “the paragraph starting on page 21, line 17 describes the addition of an electron transfer moiety to nucleosides. The paragraph starting on page 21, line 29 describes the making of a 2’ or 3’ modified nucleotide triphosphate. Furthermore, the paragraph starting on page 33, line 3 describes the use of ruthenium or iron (as well as other metals) as part of the transition metal complex”, the specification does not adequately describe that a nucleotide triphosphate comprising a covalently attached transition metal complex which is an electron transfer moiety as recited in claims 21-32. Second, although the same rejection has been withdrawn by previous examiner Zitomer, this does not mean that the examiner must agree with the decision made by examiner Zitomer.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigel *et al.*, (Inorg. Chem., 26, 2149-2157, 1987).

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Regarding claim 21, since according to the specification, “electron donor moiety” and “electron acceptor moiety” are “molecules capable of electron transfer under certain conditions. It is to be understood that electron donor and acceptor capabilities are relative; that is, a molecule which can lose an electron under certain experimental conditions will be able to accept an electron under different experimental conditions” (see the specification, page 15, lines 6-15), phosphate is electron donor moiety. Since Sigel *et al.*, teach a NTP-Co<sup>2+</sup> complex wherein Co<sup>2+</sup> attaches to NTP by phosphate (see Table 2 in page 2152 and page 2153, left column) and Co is a transition metal, Sigel *et al.*, teach a nucleotide triphosphate comprising a covalently attached electron transfer moiety (ie., phosphate) comprising a transition metal complex (ie., Co<sup>2+</sup>).

Therefore, Sigel *et al.*, teach all limitations recited in claim 21.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (703)872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.



Frank Lu  
Primary Examiner  
October 17, 2005